

REMARKS

The Official Action of November 28, 2007 rejected claims 1-4, 6-12, and 16 under 35 U.S.C. 102 over Becerra, *et al.*, U.S. Patent No. 6,907,280 ("Becerra") and rejected claims 1-18 under 35 U.S.C. §103 over Becerra. Applicant respectfully traverses both rejections, and specifically traverses the allegations in the Action as to the method steps that are supposedly disclosed in Becerra, and in accordance with the requirements of 37 C.F.R. §§1.111(b) and 1.119, submits the following comments to distinctly and specifically point out the unsupported nature of these rejections.

Figure 3 and col. 13, lines 38-41 and col. 14, lines 48-55 of Becerra describe the brain regions investigated in that patent. These brain regions make up the reward network and do not relate to memory, Alzheimer's disease (AD), or brain injury as contemplated by the method of the present invention. Specifically, the present invention does not measure metabolic activity in the primary nodes in the posterior cingulate and posterior parietal cortex, nor does the method of the present invention involve increases and decreases in resting baseline activity, all as described in Becerra.

Becerra does not disclose a method of producing an index of brain functionality using PET; instead, all the examples given in Becerra use fMRI type of brain imaging activity. fMRI has a temporal constraint of less than 4 seconds and lower time constraints are critical to the type of experimentation described in that patent. The brain activity intrinsic to the scan reflects the behavior or thoughts ongoing during the one-minute epoch of the experimental paradigm (in the examples given in Becerra, this brain activity relates basically to pain or reward-based decision making). By contrast (and as specifically called out in claim 2 of the present application), the present invention relates only to [18F]-fluoro-deoxyglucose (FDG) PET, which is characterized by a temporal constraint such that the type of activation/response-based experimental paradigm described in Becerra is quite impossible. As described in the captioned application (page 23, lines 1-7), the patient is resting quietly in a bed for an hour (not a minute as contemplated in Becerra), and then an FDG-PET brain scan is obtained "in standard clinical fashion" (quoting from page 23 of the specification) over 5 to 20 minutes. The brain activity intrinsic to the scan reflects the resting state brain activity of the patient over the entire hour that the patient is sedentary. FDG-PET therefore, is not a compatible means of carrying out the type of experimentation described in Becerra.

In short, the present invention does not measure brain activity in response to anything. Patients must be at rest, and although it was considered inherent such that it was a part of the claims as filed, to clarify how the claims of the present invention already defined over Becerra,

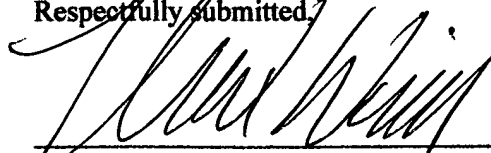
independent claims 1 and 16 have been amended to recite that image data is obtained in a patient at rest. The method described in Becerra looks at activation in a network. Some regions may be less activated than others, but the regions are not studied in the resting state.

The method of the present invention is also different than the method described in Becerra in that it weights regions based upon degree of abnormality across the group, looks at a ratio of the sum of the mean, weighted volumes of interest (VOIs), and then normalize to the standard. Becerra does not weight VOI values, does not look at summed VOI data, and does not look at summed VOI ratios. Reconsideration and withdrawal of both the §102 and §103 rejections of the claims is respectfully requested in light of these several differences between Becerra and the present invention.

Additional amendments have been made throughout the claims to improve their form and to broaden the claims, and not for the purpose of defining over Becerra. Claim 1, for instance, has been amended to make it clear that image data from selected regions of the brain of a patient being tested for cognitive decline are compared to data from the brains of group of control subjects. The step of weighting the data has been deleted from independent claim 1 because that step is not needed to define over Becerra and because, as set out at page 29, lines 10-11 of the captioned application, this step was not needed to differentiate the patients from the control group. However, that step is recited in new dependent claim 19 because weighting the data did optimize results (as described in the paragraphs following lines 10-11 of page 29).

Entry of the above amendments to the claims and the new claims, consideration of the remarks set out herein, reconsideration and withdrawal of the rejections, allowance of the claims, and passage of the application to issuance are all respectfully requested. In the unforeseen event that there are questions and/or issues yet to be answered in this application, it is respectfully requested that Applicant's Attorney be contacted at the address and phone number set out below.

Respectfully submitted,



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